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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,271	01/02/2004	Andrew J. Dosmann	MSE #2652	1709

7590 12/19/2007

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EXAMINER	
TURK, NEIL N	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
12/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/750,271	DOSMANN ET AL.	
	Examiner	Art Unit	
	Neil Turk	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/19/07, 5/18/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

The disclosure is objected to because of the following informalities: Applicant's specification on page 5 describes "overillumination redirection facets 22, 24, 26, and 28", and in the following paragraph also referring to figure 2 describes "illumination redirection facets". Examiner asserts that Applicant's disclosure needs to explain and show the difference between the different types of redirection facets, or should be amended such as to describe all the facets by "overillumination" or "illumination", with respect to the disclosure of figure 2 and facets 22, 24, 26, and 28.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claim 10 requires that exactly four overillumination redirect[ion] facets are each disposed at approximately a 45 degree angle from the illumination light guide. Applicant's specification, however, as shown in paragraph [0018] of the pre-grant publication 2004/0142370 discloses four facets 22, 24, 26, and 28 that reflect input light approximately perpendicular to the illumination light guide 18. This description, however, does not disclose the respective 45 degree angle of the facets with respect to the illumination light guide. Examiner asserts that Applicant may be indirectly defining the disposition of the four facets with respect to the guide 18 by

the relative reflection of the input light being approximately perpendicular to the guide 18, but asserts that such a disclosure does not necessarily define the facets at approximately 45 degrees from the illumination light guide. Thereby, Applicant must provide proper antecedent basis in the specification for such limitations. Applicant's pregrant publication in paragraph [0020], for example, describes a single redirection facet 30 disposed at a 45 degree angle relative to the illumination light guide 18.

The amendment filed November 19th, 2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: New claims 22, 23, and 26 require more than one overillumination redirection facet disposed at 45 degrees relative to the illumination light guide. Applicant's specification, however, only describes a single overillumination redirection facet 30 disposed at a 45 degree angle with respect to the illumination light guide, as described in paragraph [0020] of the pre-grant publication.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Objections

Claim 10 is objected to because of the following informalities: claim 10 recites, "...overillumination **redirect** facets..." Examiner asserts "redirect" should be replaced by "redirection". Appropriate correction is required.

Claims 21-23 are objected to because of the following informalities: claims 21-23 recite, "...**overilluminating** redirection facets." Examiner asserts "overilluminating" should be replaced with "overillumination". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is meant by the terms "illumination light guide cross-sectional area" and "detection guide cross-sectional area". What qualifies each cross-sectional area as "illumination light guide" or "detection guide"? Are the dimensions measured in a particular way with respect to each guide in order to define such respective cross-sectional areas? Does Applicant intend to say that the illumination light guide has a cross-sectional area and that the detection guide has a cross-sectional area, wherein the cross-sectional area of the detection guide is larger than the cross-sectional area of the illumination light guide? As currently recited, the relative relationship between the detection guide cross-sectional area to the illumination light guide cross-sectional area is indefinitely defined.

Claims 2 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear what is the structural difference between an "overillumination redirection facet" and the further required "illumination redirection facet" as required by claims 2 and 24. As the claims do not set forth any further structural elements to define the illumination redirection facet, such terminology is taken to be purely nominal and any element for redirecting light will be taken to read on the limitation.

Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3,7-9, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Lemelson (4,803,992), hereafter Lemelson.

Lemelson discloses a catheter or device 10 with an elongated housing 11 that includes a cable 21 (illumination input area at the offset of the cable) formed of four separate light pipes 22 (an illumination light guide), 24, 26, and 28 (detection guide, passing light to a photoelectric detector at the output of light pipe 28; lines 25-41, col. 4). Lemelson further discloses that a cavity 16 (read window disposed approximately

perpendicular to the input light path) is formed in the front end portion 13 that allows light energy to be directed therethrough to scan fluent material, such as body fluid existing in the cavity (line 38, col. 3 – line 2, col. 4; fig. 1). Lemelson also discloses that the device contains a plurality of reflecting surfaces 14 and 15 (two overillumination redirection facets to redirect light away from the illumination light guide) for respectively receiving light energy passed through the lens 23 of light pipe 22 from a source light and is then directed to reflect off reflecting surface 15 to receiving lens of the light pipe 28 along which it passes to a photoelectric detector coupled to the other end of light pipe 28 (lines 3-54, col. 4). With regard to claim 2, Examiner asserts that reflecting surface 14 is between the illumination light guide and the read window. With regard to claim 3, reflecting surface 15 is between the read window and the detection guide. Examiner asserts that Lemelson reads on claim 24 as discussed directly above with respect to reflecting surfaces 14 and 15.

Claims 1-3, 7, 9, 21-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Meserol (EP 0254246 A2).

Meserol discloses an improved cuvette. Meserol discloses a cuvette 10 in combination with a lancet 12 (extending outwardly from read window 22), where the cuvette has a top 14 and a bottom 15, closed wall 18, access slot 20 and a cavity 22 (for fluid, such as blood) (lines 25-40, col. 4, figs 1-4). Meserol discloses that the cavity 22 may be filled with a medium such as an optically transparent gel provided with a reagent test system (lines 8-21, col. 5). Meserol also discloses integrally formed optical

elements, such as light beam 30 from source 32, which passes through the cuvette (input area and illumination light guide is defined in the optically transmissive portion of the cuvette where light enters from source 32) and is reflected by reflecting prism 50 across cavity 22 (read window disposed approximately perpendicular to the input light path) to reflecting prism 48 (reflectors 48 and 50 constitute the one or more overillumination redirection facets) and back out through the sample cuvette (detection guide is defined in the optically transmissive portion of the cuvette where light is reflected back and out of the cuvette) to optical element 36 (detection element at the outlet end of the detection guide) (lines 1-42, col. 5; lines 10-41, col. 6, figs 5&6). With regard to claim 2, reflecting prism 50 is between the illumination light guide and the read window. With regard to claim 3, reflecting prism 48 is between the read window and the detection guide. Examiner asserts that Meserol reads on claim 24 as discussed directly above with respect to prisms 50 and 48.

Claims 25 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Tyrrell et al. (6,216,022), hereafter Tyrrell.

Tyrrell discloses an implantable measurement device. Tyrrell shows in figure 6 an optical system 14 in which an optical beam enters entry window 20 (illumination input area) to mirror 30 (the illumination light guide is shown by dotted lines connected straight across from entry window 20 to exit window 22) and is then directed against a beam splitter 70 (overillumination redirection facet) that divides the incoming beam. Tyrrell further discloses that the first partial beam is directed along a reference path 54

and cell 56, and a second beam splitter 72 to mirror 58 and exit window 22. Tyrrell further discloses that the second partial beam is deflected by mirror 74 (overillumination redirection facet) along a measurement path 48 (detection guide) through measurement region 50 (read window) to another fixed mirror 76 (overillumination redirection facet), to the beam splitter 72, mirror 58, and exit window 22. Tyrrell further discloses that a shutter 78 forms an optical switch that can be moved between a reference position and a measurement position (lines 14-49, col. 4, fig. 6). Tyrrell further discloses that the housing of the implantable optical system is adapted to admit biological fluids to the measurement region (lines 19-27, col. 3, columns 10&11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lundsgaard et al. (5,525,518), hereafter Lundsgaard.

Meserol has been discussed above.

Meserol discloses a lancet for obtaining a sample, but does not disclose that the lancet is adapted to deposits the sample onto the read window.

Lundsgaard discloses a needle 20 and sampling cavity connected for determination of a blood gas parameter in which the needle draws a blood sample through aperture 21 and into the conduit 21 down through measuring chambers 300, 400, 500, 600 (lines 52-67, col. 7, fig. 3).

It would have been obvious to modify the Meserol device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample onto the read window in order to allow for direct sample deposition on to the test area, so as to

avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Naka et al. (6,001,307), hereafter Naka.

Meserol has been discussed above.

Meserol does not disclose reagent provided on the read window.

Naka discloses an optical analyzing device in which when the covering 5a is transparent and light may be irradiated through the covering, a reagent film impregnated with a reagent may be stuck on the inner surface of the covering 5a (lines 38-46, col. 10, fig. 1a-b).

It would have been obvious to modify the Meserol device to include reagent provided on the window such as taught by Naka, such that it would be obvious to place the reagent on the window (or any location), in which location the reagent will come into contact with the sample as desired for an assay with sample and reagent interacting.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson.

Lemelson has been discussed above.

Lemelson does not disclose that the detection guide cross-sectional area is larger than the illumination light guide cross-sectional area.

It would have been obvious through routine experimentation to optimize the Lemelson device to the relative cross-sectional dimensions as recited in the claim in order to provide an optimal light path through the device.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol.

Meserol has been discussed above.

Meserol does not disclose that the detection guide cross-sectional area is larger than the illumination light guide cross-sectional area.

It would have been obvious through routine experimentation to optimize the Meserol device to the relative cross-sectional dimensions as recited in the claim in order to provide an optimal light path through the device.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson in view of Lipson et al. (4,710,623), hereafter Lipson.

Lemelson has been discussed above.

Lemelson does not disclose at least three overillumination redirection facets.

Lipson discloses an optical fiber cathether with a reactive element contained therein. Lipson discloses an optical cable 12 with a hole 18 for holding a reactive element 20. Lipson discloses that a reflective coating 22 may be applied to outer surfaces of the cable, and the reflective coating may be constructed to be wavelength specific, whereby certain wavelengths of light are reflected and others are allowed to be transmitted out of the first end 14. Lipson discloses that this significantly improves the

ability of the system to quantify the desired information by reducing or eliminating wavelengths of light passing through but not interacting with the reactive element (column 4, figs. 1&2). Lipson further discloses that the amount of alteration or change in a property of the incident light 38 is dictated by the change in the property of the reactive element 20 as it interacts with the blood, or other bodily fluid. Lipson discloses that the change in the incident light 38 is a function of the reaction between the reactive element and the fluid to be analyzed(lines 53-67, columns 5; column 6). Examiner asserts that, as shown in figure 2, the reflective coating 22 covers four surfaces, which each constitute an overillumination redirection facet. Lipson further discloses that incident light 38

It would have been obvious to modify the Lemeleson device to include four overillumination redirection facets such as taught by Lipson as another design means for analyzing bodily fluid characteristics through light interaction and alterations.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson.

Meserol has been discussed above.

Meserol does not disclose at least three overillumination redirection facets.

Lipson has been discussed above.

It would have been obvious to modify the Lemeleson device to include four overillumination redirection facets such as taught by Lipson as another design means for analyzing bodily fluid characteristics through light interaction and alterations.

Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson as applied to claims 25 and 26 and in further view of Lundsgaard.

Meserol discloses a lancet for obtaining a sample, but Meserol in view of Lipson does not disclose that the lancet is adapted to deposits the sample onto the read window.

Lundsgaard have been discussed above.

It would have been obvious to modify the Meserol/Lipson device such as taught by Lundsgaard to provide the other end of the lancet for deposition of the sample onto the read window in order to allow for direct sample deposition on to the test area, so as to avoid any loss of sample incurred from taking the pierced patient's skin and wiping sample into the cavity.

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meserol in view of Lipson as applied to claims 25 and 26 and in further view of Naka.

Meserol/Lipson does not disclose reagent provided on the read window.

Naka has been discussed above.

It would have been obvious to modify the Meserol/Lipson device to include reagent provided on the window such as taught by Naka, such that it would be obvious to place the reagent on the window (or any location), in which location the reagent will come into contact with the sample as desired for an assay with sample and reagent interacting.

Allowable Subject Matter

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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